K131132

510(k) Summary

MAY 3 1 2013

Proprietary Name:	Pelvis II Implant System
Common Name:	Bones Screws Bone Plates
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Device Class:	Class II
Product Code(s):	HRS: Plate, Fixation, Bone HWC: Screw, Fixation, Bone
For Information Contact:	Elijah N. Wreh Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: 201-831-5691 Fax: 201-831-4691
Date Prepared:	April 22, 2013

Description:

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the new Pelvis II Implant System. The Pelvis II Implant System is an internal fixation device that consists of three different types of plates used with compatible screws to fit different types of fractures in the pelvis. The subject components will be available sterile and non-sterile.

Intended Use:

The Pelvis II Implant System is intended for reconstruction, stabilization and rigid fixation of fractures in the pelvis in adult patients.

Indications for Use:

Indications for the Pelvis II Implant System will include fractures of the following regions of the pelvis:

- Anterior Column
- Anterior Column combined with posterior hemi-transverse
- Quadrilateral surface

Summary of Technologies:

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following device:

- K001614 – Stryker Trauma Pelvic Set

Non-Clinical Testing:

Non-clinical laboratory testing was performed for the Pelvis II Implant System components to determine substantial equivalence. Testing demonstrated that the Pelvis II Implant System is substantially equivalent to the predicate device currently cleared for marketing.

The following test was performed:

- Stryker Pelvis II Static and Fatigue Plate Testing

Clinical Testing:

Clinical testing was not required for this submission:

Conclusion:

The Pelvis II Implant System is substantially equivalent to the predicate device identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Trauma AG
% Mr. Elijah Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Letter dated: May 31, 2013

Re: K131132
Trade/Device Name: Pelvis II Implant System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 1, 2013
Received: May 2, 2013

Dear Mr. Wreh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K131132

Device Name: Pelvis II implant System

Indications for Use:

Indications for the Pelvis II implant System will include fractures of the following regions of the pelvis ring:

- Anterior Column
- Anterior Column combined with posterior hemi-transverse
- Quadrilateral surface

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices